



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

iCAD, Inc.  
% Mr. John A. DeLucia  
Vice President, Regulatory Affairs, Clinical Affairs and Quality Assurance  
98 Spit Brook Road, Suite 100  
NASHUA NH 03062

September 5, 2014

Re: K141343  
Trade/Device Name: Axxent® Cervical Applicator  
Regulation Number: 21 CFR 892.5900  
Regulation Name: X-ray radiation therapy system  
Regulatory Class: II  
Product Code: JAD  
Dated: July 24, 2014  
Received: July 25, 2014

Dear Mr. DeLucia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". To the left of the signature is a stylized blue and grey logo that includes the letters "FDA".

for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K141343

Device Name: Axxent® Cervical Applicator

Indications For Use:

Indications for Use: The Axxent Cervical Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver high dose rate brachytherapy for intracavitary treatment of cancer of the uterus, cervix, endometrium and vagina.

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

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## Section 5: 510(K) Summary

K141343

### **510(k) OWNER:**

iCAD Inc.  
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F: 603- 880-3843  
Registered Establishment Number: 1225671

### **MANUFACTURER FACILITY:**

Xoft Inc. a Subsidiary of iCAD Inc.  
101 Nicholson Lane  
San Jose, CA 95134  
Registered Establishment Number: 3005594788

### **NAME OF CONTACT:**

John A. DeLucia  
VP, Regulatory Affairs, Clinical Affairs and Quality Assurance  
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**DATE SUMMARY PREPARED:** May 28, 2014

**TRADE NAME:** Axxent® Cervical Applicator

**COMMON NAME:** Brachytherapy Cervical Applicator

**CLASSIFICATION:** Class II

**CLASSIFICATION NAME:** X-Ray Radiation Therapy System and Accessories

**CRF CLASSIFICATION:** 21 CFR 892.5900

**PRODUCT CODE:** JAD

## SECTION 5: 510(K) Summary (con't)

### Legally Marketed Device to Which Substantial Equivalence is Claimed

The Axxent Cervical Applicator was originally cleared under K123442. The Axxent Cervical Applicator was found substantially equivalent to the following legally marketed predicate device. In this pre-market clearance submission, iCAD Inc. is seeking clearance for adding MRI compatibility and MR Conditional labeling for which the predicate is also cleared for.

Device Name	Manufacturer	510(k) Reference #	Concurrence Date
Mick Radio-Nuclear Instruments, Inc. Modified Henschke HDR Cervix Applicator	Mick Radio-Nuclear Instruments, Inc.	K040704	06/18/2004

### Device Description

The Axxent Cervical Applicator is a component of the Axxent Electronic Brachytherapy System (cleared under K122951) which utilizes a proprietary miniaturized X-ray source and does not require radioactive isotopes. The applicator allows the Axxent HDR X-ray source to deliver high-dose rate, low energy radiation treatment to the uterus, cervix, endometrium and vagina. The Axxent HDR X-ray source mimics the penetration and dose characteristics of Iridium-192.

The Axxent Cervical applicator is provided non-sterile and can be reused. The user must sterilize the device using steam sterilization before each use. An Applicator Clamp is a required accessory to stabilize the Cervical Applicator during radiation treatment.

### Intended Use / “Indications for Use”

The indications for use have not changed since its clearance under K123442. The Axxent Cervical Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver high dose rate brachytherapy for intracavitary treatment of cancer of the uterus, cervix, endometrium and vagina.

## **Summary of Technological Characteristics**

The technological characteristics of the Axxent Cervical Applicator have not changed since its clearance under K123442. In this pre-market clearance submission, iCAD Inc. is seeking clearance for adding MRI compatibility and MR Conditional labeling to the Instructions for Use. The Axxent Cervical Applicator is substantially equivalent to the predicate device, Mick Radio-Nuclear Instruments, Inc. Modified Henschke HDR Cervix Applicator, in terms of MR compatibility.

## **General Safety and Effectiveness Concerns**

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis which is used to identify potential hazards. Any potential hazards are controlled through development, verification and validation testing.

## **Assessment of Non-Clinical Performance Data**

A study report was included in this submission which evaluated the Axxent Cervical Applicator for MRI compatibility in 1.5 T and 3 T clinical scanners. Test samples were provided in their final manufactured condition and were evaluated for the following:

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213 as a guide)
3. MR image artifact (ASTM F2119)
4. Radiofrequency induced heating (ASTM F2182)

The results of the testing indicated that, in accordance with the guidance of relevant ASTM standards, Xoft's Cervical Applicator should be labeled MR Conditional.

## **Conclusion**

This traditional 510(k) for the Axxent® Cervical Applicator contains adequate information and data to determine substantial equivalence to the predicate device.